

Patent
10/086,585

REMARKS

Claims 1-7, 9-10, 12-54 are now pending in the application, with Claims 3-5 and 18-54 withdrawn from consideration. Claims 1, 2, 6-7, 9-10 and 12-17 are the claims under consideration.

Independent Claim 1, the only independent claim under consideration, has been amended herein.

Claims 8 and 11 have been canceled, and the limitations thereof have been incorporated into amended independent Claim 1.

Claims 9, 12, 14 and 15 have been amended to correct dependency.

Section 101 Rejection

Claims 1, 2 and 6-17 were rejected under 35 USC 101 as being directed to non-statutory subject matter. Specifically, the Action states that "Claim 1 recites the introducer sheath as *partially contacting tissue* - [t]he human body is non-statutory subject matter".

In response, independent Claim 1 has been amended herein to recite that "in use, the device is adapted to be positioned such that the ablation catheter contacts tissue to be treated and the introducer sheath contacts tissue to be protected".

This claim amendment is believed to overcome the Section 101 rejection and reconsideration and withdrawal of that rejection are respectfully requested.

Section 102(b) and 103(a) rejections

Claims 1, 2, 8 and 9 were rejected under 35 USC 102(b) as being anticipated by US Patent 6,595,9889 (Schaer); Claims 6 and 7 were rejected under 35 USC 103(a) as being unpatentable over Schaer in view of US Patent 4,949,460 (Merry et al.); and Claims 10, 16 and 17 were rejected as being unpatentable over Schaer in view of US Patent 5,868,735 (Lafontaine).

In view of the foregoing claim amendments and the following discussion, each of the rejections is traversed and reconsideration is respectfully requested.

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First, Applicants note that dependent Claims 11-15 were not rejected based on prior art – but only based on the Section 101 rejection noted and addressed above. The limitations of dependent Claim 11 (and those of intervening dependent Claim 8) have been incorporated into amended independent Claim 1. For at least this reason, Claim 1 is believed patentable over the art of record and to be clearly in condition for allowance.

Independent Claim 1, as amended herein, is directed to a device to treat tissue while preventing tissue damage to adjacent tissue, including an ablation catheter, including a guidewire lumen, a supply lumen and a return lumen, a tubular introducer sheath for the ablation catheter, wherein the ablation catheter is inserted through and extends past a distal end of the introducer sheath, and further wherein, in use, the device is adapted to be positioned such that the ablation catheter contacts tissue to be treated and the introducer sheath contacts tissue to be protected, a heater disposed adjacent or within the introducer sheath, the heater thermally coupled to the tissue, a source of cryofluid having a supply tube and a return tube, the supply tube coupled in fluid communication to the supply lumen and the return tube coupled in fluid communication to the return lumen and a control unit for the heater.

Schaer fails to teach or suggest a device to treat tissue and prevent damage to adjacent tissue that includes a catheter having a guidewire lumen/a supply lumen/a return lumen, a tubular introducer sheath for the ablation catheter, a heater disposed adjacent or within the introducer sheath, a source of cryofluid having a supply tube and a return tube, the supply tube coupled in fluid communication to the supply lumen and the return tube coupled in fluid communication to the return lumen; and a control unit for the heater.

For each of the foregoing reasons, Applicants submit that independent Claim 1, as amended herein, is patentable over Schaer.

Dependent Claims 2, 6-7, 9-10 and 12-17 are believed to be clearly patentable for all of the reasons indicated above with respect to amended independent Claim 1, from which they depend, and even further distinguish over the cited references by reciting additional limitations.

Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the

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Applicants' undersigned attorney at (908) 518-7700 in order that any outstanding issues be resolved.

Respectfully submitted,


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